

Attorney Docket No.: PENN-0789  
Inventors: Siegel et al.  
Serial No.: 10/046,504  
Filing Date: October 19, 2001  
Page 6

#### REMARKS

Claims 1-10 are pending in the instant application. Claim 1-10 have been rejected. Claims 1, 3 and 4 have been amended. Claims 2 and 5 have been canceled in light of the amendments to claims 1 and 4. Support for these amendments is provided in canceled claims 2 and 5 and in the specification at page 8, lines 23-27, page 9, line 23 through page 12, line 13. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **I. Rejection of Claims 2 and 3 under 35 U.S.C. 112, second paragraph**

Claims 2 and 3 have been rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that there is insufficient antecedent basis for the comprising language in these claims.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 3 to remove the comprising language. Further claim 1 has been amended to state that the biodegradable polymer or copolymer is selected from the group consisting of polylactide and

Attorney Docket No.: PENN-0789  
Inventors: Siegel et al.  
Serial No.: 10/046,504  
Filing Date: October 19, 2001  
Page 7

lactide-co-glycolide copolymer and claim 2 has been canceled.

Withdrawal of this rejection under 35 U.S.C. 112, second paragraph, is therefore respectfully requested.

**II. Rejection of Claims 1-10 under 35 U.S.C. 35 U.S.C. 103(a)**

Claims 1-10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al. (U.S. Patent 6,166,173). The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the biodegradable implant of Mao by compression molding of discs or melt process and incorporate the amount of active agent of haloperidol or clozapine or risperidone antipsychotic drugs in an amounts of from 1-65% that would be effective to product the desired antipsychotic effect.

Applicants respectfully traverse this rejection.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally the prior art

Attorney Docket No.: PENN-0789  
Inventors: Siegel et al.  
Serial No.: 10/046,504  
Filing Date: October 19, 2001  
Page 8

reference must teach or suggest all the claim limitations. See MPEP 2143. Mao et al. (U.S. Patent 6,166,173) does not meet these basic criteria.

Claims 1 and 4 of the instant application have been amended to state that the biodegradable polymer or copolymer is selected from the group consisting of polylactide and lactide-co-glycolide copolymer. Support for this amendment is provided in claims 2 and 5, now canceled, and in teachings of the specification at page 8, lines 23-27, page 9, line 23 through page 12, line 13.

In contrast, teachings of Mao relate to use of a biodegradable polymer composition containing both phosphate and ester linkages. Formulas I and II of Mao et al. both contain a phosphorus atom in their backbone and their Y-L-Y sequence is different from the random polylactide and lactide-co-glycolide copolymers used in the present invention.

Thus, the Mao reference fails to teach or suggest all the limitations of the instant claims.

Further, while Mao discloses a string list of potential drugs which may be delivered using their biodegradable polymer composition, no data whatsoever regarding stability and/or release and/or undesirable side effects such as tissue necrosis are presented for any of the listed exemplary antipsychotic agents. As taught beginning at line

Attorney Docket No.: PENN-0789  
Inventors: Siegel et al.  
Serial No.: 10/046,504  
Filing Date: October 19, 2001  
Page 9

14, page 12 of the instant application, not all pharmaceutical agents or antipsychotic agents were found to be amenable to the delivery system of the present invention.

Thus, teachings of Mao et al. also fail to provide any reasonable expectation of success with respect to the instant claimed invention.

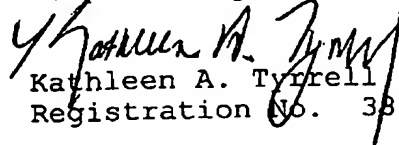
Accordingly, the Mao reference fails to meet the three basic criteria required to establish a prima facie case of obviousness with respect to the instant invention.

Withdrawal of this rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

### III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

Date: August 3, 2006

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515